IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
Atlanta Division

LINDA MORGAN, Plaintiff, v. JOHNSON & JOHNSON and ETHICON, INC., Defendants.	Civil Action No.

PLAINTIFF'S COMPLAINT AND JURY DEMAND

Plaintiff Linda Morgan ("Plaintiff" or "Ms. Morgan") brings this Complaint and Jury Demand against Johnson & Johnson ("J&J") and Ethicon, Inc. ("Ethicon") (collectively "Defendants") alleging the following:

NATURE OF ACTION

1. This action seeks to recover damages for injuries sustained by Plaintiff as the direct and proximate result of the wrongful conduct of Defendants in connection with the designing, developing, distributing, labeling, advertising, marketing, promoting, and selling a mesh product known as Gynecare Gynemesh PS ("Gynemesh PS").

PARTIES

2. Plaintiff suffered damages as a result of Defendants' intentional and negligent conduct, and she is and was, at all material times, a citizen and resident of Georgia.

3. Defendant J&J is a New Jersey corporation and a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices such as Gynemesh PS.

4. Defendant Ethicon is a "Business Unit" and wholly owned subsidiary of Defendant J&J and researched, designed, developed, promoted, marketed, tested, and distributed Gynemesh PS.

JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) as there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000.00 exclusive of interest and costs.

6. Defendants have significant contacts with this federal judicial district and therefore they are subject to the personal jurisdiction of the Court in this district.

7. Specifically, Defendants placed medical devices into the stream of commerce by designing, manufacturing, advertising, promoting, and selling the

defective Gynemesh PS product, including the product implanted in Plaintiff in this district.

8. At all relevant times, Defendants labeled and packaged the Gynemesh PS product, including the product which was implanted in Plaintiff in this district.

9. Defendants have transacted business within the state of Georgia.

10. Defendants have purposefully and systematically committed acts and consummated transactions in the state of Georgia from which they have derived and continue to derive substantial revenue, and they have otherwise committed purposeful actions in the state of Georgia.

11. A substantial part of the events and omissions giving rise to Plaintiff's claims occurred in this federal district and therefore, pursuant to 28 U.S.C. § 1391(b)(2), venue is proper in this district.

12. Specifically, Plaintiff's initial surgery during which she was implanted with Defendants' defective Gynemesh PS product occurred in the Northern District of Georgia.

13. Plaintiff resided in the Northern District of Georgia at the time Plaintiff began to experience symptoms associated with the defective mesh product developed, manufactured, and sold by Defendants, and when she underwent her excision procedure.

14. The products at issue in this lawsuit failed due to defects in design in the Northern District of Georgia.

FACTS

A. Plaintiff Linda Morgan was injured by Defendants' defective and unreasonably dangerous mesh products.

15. Ms. Morgan was implanted with Defendants' Gynemesh PS product by Dr. Robert Kovac at Emory University Hospital in Atlanta, Georgia on March 13, 2009.

16. The implanted Gynemesh PS was intended to treat Ms. Morgan's stress urinary incontinence.

17. The Gynemesh PS product was utilized and implanted in a manner foreseeable to Defendants using Defendants' instructions for use and procedures for implantation.

18. Following the implant surgery, Ms. Morgan experienced several complications such as vaginal bleeding, persistent granulated tissue, and mesh exposure.

19. On December 10, 2010, after conservative treatment, Ms. Morgan underwent an excision procedure, which she understood to be a mesh removal surgery.

20. Between 2011 and 2018, Ms. Morgan experienced occasional bleeding, pelvic pressure, and frequency. During this timeframe, Ms. Morgan underwent pelvic exams and understood her condition to be normal and not worrisome.

21. In April 2021, Ms. Morgan began to experience heavy vaginal bleeding. An MRI in May 2021 revealed the Gynemesh PS had eroded into her vaginal canal. and the surrounding area was inflamed.

22. Upon receiving a referral, Ms. Morgan consulted with a urogynecologist, who confirmed Ms. Morgan had excessive granulated tissue and observed the eroded Gynemesh PS.

23. On September 21, 2021, Ms. Morgan underwent an excision procedure performed by Dr. Gina Northington. This was a complicated procedure with significant blood loss.

24. In the post-operative report, the excision surgeon confirmed that Plaintiff had prior mesh exposure but was otherwise asymptomatic until her significant vaginal bleeding in 2021.

25. The mesh implanted in Ms. Morgan's mesh exposure, severe bleeding, and development of granulated tissue caused a severe chronic foreign body reaction, which was ongoing, latent, and did not manifest as a discoverable injury until 2021.

26. The occurrence of a severe chronic foreign body reaction is documented in the pathology reports and surgical reports from 2021.

27. Despite undergoing the extensive excision procedure, Ms. Morgan continues to experience intermittent bleeding, pain, and recurrent incontinence. Her treatment is ongoing.

28. As a result of having the Gynemesh PS product implanted in her, Ms. Morgan has experienced significant mental and physical pain, disability, suffering, permanent injuries, substantial physical deformity, and has suffered financial loss, including, but not limited to obligations for medical services and expenses.

B. <u>The unreasonably dangerous nature of Defendants' Gynemesh PS.</u>

29. In 2002, Defendants launched Gynemesh PS.

30. Scientific evidence pre-dating and post-dating the product launch shows that the polypropylene mesh used in mesh products, like Gynemesh PS, is biologically incompatible with human tissue.

31. The polypropylene mesh used in Gynemesh PS promotes an immune response in many women, which can degrade the mesh and pelvic tissue.

32. The serious immune response the polypropylene mesh used in Gynemesh PS also causes chronic pelvic tissue inflammation, shrinkage, or

contraction of the mesh leading to nerve entrapment, further inflammation, chronic infections, and chronic pain.

33. Due to the unreasonably dangerous nature of Gynemesh PS, women like Plaintiff can experience significant urinary dysfunction, vaginal shortening, and anatomic deformation as well.

34. The specific defects posed by Gynemesh PS include, but are not limited to, the following:

a. The use of polypropylene material in the product and the immune reactions that result from such material, causing adverse reactions, and injuries;

b. No procedure had been designed for safe, effective removal of the product;

c. Biomechanical issues with the design of the product, including, but not limited to, the propensity of the product to contract or shrink once implanted causing surrounding tissue to be inflamed, fibrotic, and contracted;

d. The rigid nature of the product causes it to become improperly mated to the delicate and sensitive areas of the vagina and pelvic causing pain during normal daily activities involve movement of the pelvic area;

e. The mesh utilized in Gynemesh PS is too heavy for its purpose;

f. The pores of the mesh utilized in Gynemesh PS are too small for its purpose;

g. The propensity of the product to degrade or fragment over time, which can cause a chronic inflammatory and fibrotic reaction resulting in injury; and,

h. The adverse tissue reactions caused by the product is causally connected to more frequent infection.

35. At all material times Defendants knew their Gynemesh PS product was unreasonably dangerous.

36. As a result of being implanted with Defendants' unreasonably dangerous mesh product, Plaintiff experienced a chronic foreign body response, inflammation, mesh erosion, pelvic pain, and bleeding.

C. Defendants knew or should have known their Gynemesh PS were defective and unreasonably dangerous and failed to warn.

37. Defendants failed to conduct adequate testing to ensure Gynemesh PS was reasonably safe for implantation in the female pelvic area before attempting to introduce this product into the market.

38. At all relevant times, Defendants knew or should have known of the significant risks and high complication rate posed by implanting Gynemesh PS into the female body.

39. Defendants willfully suppressed relevant information about the serious risks posed by products utilizing Gynemesh PS mesh. For instance:

a. Defendants concealed information about the risk of dyspareunia;

b. Defendants declined internal requests to improve their information for use ("IFU") disclosures;

c. Defendants avoided learning negative information about its mesh products;

d. When notified by the FDA in 2008 of the significant risks posed by mesh like the Gynemesh PS, Defendants did not proactively engage with implanting providers or consumers;

e. Defendants did not warn that complete removal of the product may not be possible and may not result in complete resolution of complications;

f. Defendants did not warn of the potential need for mesh removal until 2015—long after Ms. Morgan's implant;

g. Defendants did not warn of the need for multiple revisions or significant dissection during revision surgery until 2015—long after Ms. Morgan's implant.

h. Defendants did not—and have never—warned of the potential for post-operative side effects that could impact quality of life and daily routine.

40. Defendants nevertheless marketed Gynemesh PS directly to its potential patient population through patient brochures, in-office patient counseling materials, internet advertising, public relations events, etc. The goal of this marketing was to create consumer demand.

41. Defendants likewise aggressively marketed to doctors.

42. At all relevant times, Defendants downplayed the risks posed by their mesh products and warnings about the products from the FDA. This is particularly notable in Defendants' representations regarding the rate, manner, and severity of erosion/extrusions and the permanency of issues stemming from these products.

43. Defendants cultivated the impression that its mesh products, like Gynemesh PS, were safer and more effective than non-mesh approaches to treating stress urinary incontinence.

44. Defendants provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing their pelvic mesh products.

45. As a result of Defendants providing incomplete and misleading information about Gynemesh PS to physicians, such providers disseminated inadequate and misleading information to their patients.

46. Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff, her providers, and the general public on notice of the dangers and adverse effects caused by the implantation of Gynemesh PS.

47. Defendants knew Gynemesh PS was defective and unreasonably dangerous but continued to manufacture, market, distribute, and sell these products to maximize sales and profits at the expense of health a safety.

48. Defendants' acts were willful, reckless, and wanton, and the proximate cause of Plaintiff's injuries.

D. Defendants profited from their defective product.

49. When Plaintiff underwent the surgical implant of Defendants' Gynemesh PS product, Defendants enjoyed financial gain by accepting payment for the devices by Plaintiff by others on her behalf.

50. Plaintiff did not receive safe or effective products for which Defendants were compensated by Plaintiff or by others on her behalf.

51. The product, as set forth above, caused her severe medical problems.

52. Despite this inequity, Defendants retained the money paid for the defective products by Plaintiff or by others on her behalf.

CAUSES OF ACTION

COUNT I
Strict Liability - Design Defect

53. Plaintiff incorporates by reference each and every material fact of this Complaint as if set forth fully herein.

54. Defendants' Gynemesh PS product, which was implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design.

55. As previously stated, the product's design defects include, but are not limited to:

a. The use of polypropylene in the product;

b. The product tends to degrade, shrink, and fragment;

c. The mesh used in the product is too heavy;

d. The pore size of the mesh used in the product is too small;

e. No standardized removal process exists;

f. Full removal of the mesh may not be possible;

g. Patients have experienced severe reactions at a high rate.

56. FDA documentations, health advisory warnings, and medical research confirm such complications and defective properties in the Gynmesh PS product and other substantially similar products.

57. As a direct and proximate result of Gynmesh PS' aforementioned defects as described herein, Ms. Morgan has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

58. Ms. Morgan experienced permanent injuries caused by Defendants' Gynmesh PS product before removal and as a result of removal.

59. Ms. Morgan will continue to suffer the above-referenced and new injuries until death.

60. Defendants are strictly liable to the Plaintiff for the defective design of these products.

61. Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, punitive damages, and such further relief as the Court deems equitable and just.

COUNT II
Strict Liability – Failure to Warn

62. Plaintiff incorporates by reference each and every material fact of this Complaint as if set forth fully herein.

63. The Gynmesh PS products implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings.

64. Defendants were aware that Gynemesh PS, as described herein, degrades, contracts, shrinks, frays, cords, migrates, stiffens, and/or otherwise deforms at all times relevant to Plaintiff's claims.

65. Defendants owed a duty to Plaintiff at all material times to warn of its product's known characteristics or defective propensities as described herein.

66. Defendants breached and continue to breach the duties owed to Plaintiff, her medical providers, the medical community, and/or the public by providing incomplete, insufficient, and misleading training and information to physicians and the medical community.

67. Defendants' failure to provide sufficient, correct, or complete information led to the dissemination of inadequate and misleading information to patients, including Plaintiff.

68. Defendants did not disclose and hid the magnitude and frequency of problems associated with Gynemesh PS from implanting physicians.

69. Like Plaintiff, implanting physicians relied on the limited information provided by Defendants in selecting their products for treatment and would have

made different treatment recommendations had they known the true magnitude and frequency of the risks associated with Gynemesh PS.

70. Defendants provided inadequate warnings to Plaintiff's physician, who relied on them in deciding to implant her with Gynemesh PS.

71. Defendants' failure to warn caused Plaintiff's injuries.

72. Defendants are liable to Plaintiff in strict liability for failure to warn.

73. Plaintiff will continue to suffer the above-referenced and new injuries until death.

74. Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, punitive damages, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
Negligence

75. Plaintiff incorporates by reference each and every material fact of this Complaint as if set forth fully herein.

76. Defendants owed a duty to exercise reasonable and ordinary care in the design, labeling, instructions, warnings, sale, marketing, and distribution of Gynemesh PS, as well as the recruitment and training of physicians to implant these products in women.

77. Defendants had a further duty to provide adequate and sufficient instructions concerning the proper use of the Gynemesh PS, as well as warnings regarding the risks and dangers associated with using these products to Plaintiff and other foreseeable users of these products.

78. Defendants, however, breached their duty of care and were negligent in the design, labeling, warning, instruction, training, selling, marketing, and distribution of Gynemesh PS in one or more of the following ways:

a. Failing to design the Gynemesh PS so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including Plaintiff;

b. Failing to use reasonable care in the testing of Gynemesh PS, so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including Plaintiff;

c. Failing to use reasonable care in inspecting the Gynemesh PS, so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including Plaintiff;

d. Failing to use reasonable care in training its employees and healthcare providers related to the use of the products, so as to avoid an unreasonable risk of harm to women in whom the Gynemesh PS was implanted, including Plaintiff;

e. Failing to use reasonable care in instructing and/or warning the public, health care providers, and patients, including Plaintiff, as set forth herein of risks associated with Gynemesh PS, so as to avoid an unreasonable risk of harm to women in whom these products were implanted, including Plaintiff;

f. Failing to use reasonable care in marketing and promoting the Gynemesh PS, so as to avoid an unreasonable risk of harm to women in whom these products were implanted, including Plaintiff;

g. In negligently and carelessly promoting the use of the Gynemesh PS to physicians who had not received sufficient training to master the techniques necessary for the implantation of the device into women, including Plaintiff;

h. Failing to develop a safe, effective removal process in the event of failure, injury, or complication;

i. Choosing to use polypropylene material in its Gynemesh PS which was known to incite a chronic inflammatory response in women;

j. Selling Gynemesh PS when it knew or should have known that the warnings included were incomplete and insufficient;

k. Undermining the lack of safety and efficacy of its products in the media;

79. Otherwise negligently or carelessly designing, marketing, distributing, warning, labeling, studying, testing, or selling the Gynemesh PS

80. As a direct and proximate result of Defendants' negligence, Plaintiff was implanted with Gynemesh PS and suffered serious bodily harm.

81. Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, punitive damages, and such further relief as the Court deems equitable and just.

COUNT IV
Fraudulent Concealment

82. Plaintiff incorporates by reference each and every material fact of this Complaint as if set forth fully herein.

83. At all relevant times, Defendants misrepresented the safety of Gynemesh PS for its intended use.

84. It was known or should have been known to Defendants that Gynemesh PS caused large numbers of serious complications and that the efficacy rate of the product meant that it was not safe or effective.

85. Despite Defendants' knowledge of problems and defects with their product, Defendants continued to represent Gynemesh PS as being safe.

86. Defendants knew or was reckless in not knowing that their representations were false.

87. Defendants were under a duty to disclose to Plaintiff, her physicians, hospital, healthcare providers, and/or the FDA the defective nature of Gynemesh PS.

88. Defendants had sole access to the material facts concerning the defective nature of the product and its propensity to cause serious, dangerous side effects resulting in damage to Plaintiff who was implanted with Gynemesh PS.

89. Defendants were in a superior position to know the true safety and efficacy of Gynemesh PS.

90. Defendants continued to make knowingly false statements in documents and marketing materials regarding the safety and efficacy of its products.

91. Defendants fraudulently and affirmatively concealed the defective nature of Gynemesh PS from Plaintiff.

92. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff and her physician with the intent to defraud them.

93. Defendants knew Plaintiff and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions.

94. Plaintiffs and her doctors, healthcare providers, and/or hospitals reasonably relied on Defendants' false information and marketing materials.

95. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Gynemesh PS.

96. Plaintiff acted diligently in consulting with her medical providers regularly.

97. Due to Defendants' fraudulent concealment, Plaintiff did not discover, nor should she have discovered, facts sufficient to put her on notice of a potential cause of action stemming from a defective mesh product until 2021.

98. As a result of the foregoing acts and omissions, Plaintiff suffered severe physical pain and mental anguish.

99. Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, punitive damages, and such further relief as the Court deems equitable and just.

COUNT V
Negligent Misrepresentation

100. Plaintiff incorporates by reference each and every material fact of this Complaint as if set forth fully herein.

101. Defendants incurred a duty to accurately represent to the medical and healthcare community, Plaintiff, and the public that the Gynemesh PS had not been adequately tested and found to be safe and efficacious.

102. Defendants breached this duty by misrepresenting and actively concealing adverse information within its actual or constructive knowledge regarding the Gynemesh PS defects and unreasonably dangerous qualities.

103. Defendants negligently and/or intentionally misrepresented or omitted necessary and required information in the product labeling, promotions, and advertisements.

104. These misrepresentations were untrue and misleading.

105. Defendants knew or should have known of the falsity or misleading nature of its misrepresentations.

106. Defendants nevertheless made these misrepresentations about the Gynemesh PS' safety and efficacy with the intent that Plaintiff and/or her providers would rely on them, leading to the implantation of these products in her body.

107. At the time of Defendants' misrepresentations, neither Plaintiff nor her providers knew of the falsity of Defendants' misrepresentations.

108. As a result of Defendants' misrepresentations, Plaintiff suffered severe physical pain and mental anguish.

109. Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, punitive damages, and such further relief as the Court deems equitable and just.

COUNT VI
Unjust Enrichment

110. Plaintiff incorporates by reference each and every material fact of this Complaint as if set forth fully herein.

111. At all relevant times, Defendants designed, sold, and/or supplied Gynemesh PS.

112. Plaintiff paid for Gynemesh PS to treat stress urinary incontinence.

113. Defendants held these products out as being safe and effective and meant to treat the aforementioned conditions.

114. Defendants accepted payment by Plaintiff and/or others on behalf of Plaintiff for the purchase of Gynemesh PS.

115. Plaintiff did not receive the safe and effective Gynemesh PS for which she paid.

116. It would be inequitable for Defendants to keep this money since Plaintiff did not receive safe and effective products.

117. Plaintiff demands judgment against Defendants and requests monetary restitution.

COUNT VII
Punitive Damages

118. Plaintiff incorporates by reference each and every material fact of this Complaint as if set forth fully herein.

119. Defendants showed utter indifference and conscious disregard for Plaintiff and the public's safety because they knew Gynemesh PS was unreasonably dangerous in light of the severe and permanent complications associated with the product.

120. Despite its knowledge of the danger, Defendants continued to sell the products to maximize profits and the expense of patients', like Plaintiff's, health.

121. Defendants' tortious actions and omissions willful misconduct, intentional conduct, reckless conduct, fraudulent conduct, malice, wantonness, oppression, and the entire want of care that would raise the presumption of a conscious indifference to the consequences of their actions as defined by O.C.G.A. § 51-12-5.1 and relevant case law.

122. Defendants' conduct injured Plaintiff.

123. An award of punitive and exemplary damages against Defendants to punish, penalize, and deter these Defendants and others similarly situated from repeating such egregious conduct in the future is justified. This request for punitive

damages includes, but is not limited to, damages allowable under a finding that Defendants acted or failed to act with specific intent to cause harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants and requests:

A. Compensatory damages in excess of the minimum jurisdictional amount, including, but not limited to, compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined by the triers of fact in this action;

B. Economic damages in the form of medical expenses, out-of-pocket expenses, life care expenses, and other economic damages in an amount to be determined by the triers of fact in this action;

C. Punitive damages;

D. Attorneys' fees, expenses, and other costs of this action; and,

E. Such relief as this Honorable Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

This 9th day of June, 2022.

Respectfully submitted,

/s/ M. Alan Holcomb
M. Alan Holcomb
Georgia Bar No. 879771
Janeen E. Smith
Georgia Bar No. 377429
Turnbull, Holcomb & LeMoine, P.C.
945 East Paces Ferry Road, NE, Suite 2275
Atlanta, Georgia 30326
Telephone: (404) 793-2566
Facsimile: (404) 348-4260
Email: aholcomb@turnbullfirm.com
jsmith@turnbullfirm.com

Attorneys for Plaintiff

CERTIFICATE OF FONT COMPLIANCE

Counsel for Plaintiff hereby certifies that the foregoing has been prepared with one of the font and point selections approved by the Court: Times New Roman 14 Point.